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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,398

02/27/2004

Kathleen M. Miller

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EXAMINER

SWEET, THOMAS

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,398	<b>Applicant(s)</b> MILLER ET AL.	
	<b>Examiner</b> Thomas J. Sweet	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 1-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2009 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 73-104 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 73-74, 84, 95-97 and 103 are rejected under 35 U.S.C. 102(a) as being anticipated by Solomon et al. (6261271). Solomon et al discloses a stent comprising

(a) a polymeric tubular shaft having more than one layer (e.g. fig. 7, col 6 lines 15-22), said polymeric tubular shaft comprising a first annular layer (22) comprising an extruded homogenous mixture of a matrix polymer (abs), an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor (Chlorhexidine, one of the same materials currently disclosed for this purpose);

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(b) a first polymeric barrier layer at least partially covering an interior surface of said first annular layer (the inner of the tri-layer, col 6 lines 15-22); and

(c) a second polymer barrier layer at least partially covering an exterior surface of said first annular layer (the outer of the tri-layer, col 6 lines 15-22).

Regarding 74, stent is a ureteral stent (col 4 lines 1-7).

Regarding claims 95-97, a silver compound, (Ag EDTA, Example XIII)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-75, 80-90, 94-99 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al (US 6224579 from the IDS) in view of Solomon et al. (6261271). Modak et al discloses a ureteral stent (col 4, lines 16-36) comprising a polymeric tubular shaft having more than one layer (i.e. coating), said polymeric tubular shaft comprising a first annular layer comprising matrix polymer comprising, an antimicrobial agent (triclosan, title), and a microbial attachment/biofilm synthesis inhibitor (Ag EDTA, col 4, lines 3-14) a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer (i.e. a dip coated stent has a layer inside and out). However, Modak et al remain silent as to using

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extrusion to prepare the tubing and agent resulting in a homogeneous bulk distribution. Solomon et al. discloses another ureteral stent utilizing twin screw extrusion with a homogeneous melt for the purpose of distribution of the agent in the base polymer (abs, Solomon et al. also discloses the dip coating method as and equivalent). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the extrusion method of Solomon et al in place of the dip coating method of Modak et al in order to distribution of the agent in the base polymer. Such a modification amounts to mere substitution of one agent distribution method for another within the are of implantable tubing (ureteral stents)

Regarding claim 75, see Modak et al col 4 line 45-.1-20% triclosan.

Regarding claims 80 and 89, lubricous surface see Modak et al col 15, lines 40-45.

Regarding claims 81, obviousness of use of plural apertures in the walls of a urethral stent is now admitted prior art.

Regarding claims 82, 83 and 88, obviousness of bismuth subcarbonate as a radio-opacifying agent in the art of ureteral stents is now admitted prior art.

Regarding claims 86 and 94, obviousness of end regions of different durometer valve in the art of ureteral stents is now admitted prior art.

Regarding claims 85 and 87, obviousness of wall thickness in the .2-.8 mm range in the art of ureteral stents is now admitted prior art.

Regarding claims 97-99, Modak et al discloses “a silver compound, "(Ag EDTA) “and an anti-inflammatory agent” (salicylic acid, col 10, lines 18-21).

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Claims 76-79 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of Solomon et al as applied to claims 73 and 87 and in further view of Schwarz et al (US 2001/0022988). Modak et al as modified discloses a stent as discussed above. However, Modak et al does not disclose use of ethylene vinyl acetate copolymer. Schwarz et al discloses another stent using ethylene vinyl acetate copolymer for the purpose of holding drugs for local delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ethylene vinyl acetate copolymer of Schwarz et al for the drug polymer of Modak et al in order to locally deliver drug. Such a modification amounts to mere substitution of one functionally equivalent drug polymer for another within the art of stents.

Regarding claims 78-79, It is a matter of mere design choice to vary the percentages of drug to polymer which is not patentably distinct from the prior art.

Regarding claims 91-93, the 5-20 wt % triclosan and EVA ureteral stent as rejected above is structurally identical and therefore would function the same as the claimed stent.

Claims 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of in view of Solomon et al as applied to claims 73 and 95 and in further view of Buscemi et al (US 5693034). Modak et al as modified discloses a stent as discussed above including use of suitable hydrophilic polymer as a lubricant (col 10, lines 14-17). However, Modak et al remain silent as to the suitable hydrophilic polymer being polyacrylic acid. Buscemi et al teaches another lubricant of hydrophilic polymer using polyacrylic acid for the purpose of lubricating medical devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polyacrylic acid coating of Buscemi et al as the

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lubricous coating of Modak et al in order to lubricate the medical device. Such a modification amounts to mere substitution of one functionally equivalent lubrication coating for another within the art of medical devices.

Claims 102 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view Solomon et al as applied to claims 73 and further in view of Falk et al. (US 6048844). Modak et al as modified discloses a stent as discussed above. However, Modak et al does not disclose the use of ketorolac as an anti-inflammatory. Falk et al. discloses another stent using ketorolac for the purpose of functioning as an anti-inflammatory. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ketorolac as taught by Falk et al for the salicylic acid of Modak et al in order to function as an anti-inflammatory. Such a modification amounts to mere substitution of one functionally equivalent anti-inflammatory for another within the art of stents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/

Primary Examiner, Art Unit 3774